



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,842	08/29/2003	Bret A. Ferrec	BAF-16402/29	2836
25006	7590	07/18/2007		
GIFFORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C			EXAMINER	
PO BOX 7021			SWEET, THOMAS	
TROY, MI 48007-7021				
			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/652,842

Applicant(s)

FERREE, BRET A.

Examiner

Thomas J. Sweet

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19-25 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 19, 27, 28, 30, 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20-25, 29 and 31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's arguments filed 05/04/2007 have been fully considered but they are not persuasive. Regarding the 102/103 rejection, Buettner-Janz et al is fully capable of being used as claimed (refer to the rejection of claim 31). Applicant assumes that Buettner-Janz et al cannot be considered install and still have the space between the 3s still open. This is not the case Buettner-Janz et al is fully capable of being installed with the anchor engaging the vertebra but not embedded to the rim. Regarding claims 21 and 22, the rejection in total clearly supports rejection of these claims. Regarding claim 31, see the rejection of the claim for the requested explanation. Regarding the 103 rejection, both Buettner-Janz et al and Masini related to cementing cavities in prosthetics and Buettner-Janz et al would inherently pressurize the cement when seated, therefore it amounts to mere substitution since both introduce cement in a cavity and pressurize cement at the installation sight. Additionally, mere substitution does not require any additional motivation since it uses the same motivation as the base reference and an equivalent that results in accomplishing the same ends within a related art. Regarding claims 20-26, 29 and 31, the rejection is directed to claim 29 and therefore claim 20 and the rejection in total clearly supports rejection of these claims. The remainder of the pending claims are addressed below.

The cancellation of claim 26 renders the double patenting rejection moot.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-25 and 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buettner-Janz et al. (US 4,759,766). Buettner-Janz et al. discloses a system (figs. 2 and 5-7) including an artificial disc replacement (title) configured for placement within a vertebral disc space between opposing vertebral endplates, the ADR comprising; a component forming a cavity (at 8) between the component and one of the vertebral endplates; and a path (the channels between the 3s) is fully capable of filling the cavity with cement (8, Col 5, lines 28-30).

With regard to claims 21 and 22, the is a channel/groove is defined by the gap between the 3s

With regard to claim 23, the component includes a peripheral rim to form the cavity (as see in fig. 6, surface 2 conforms around the volume at 8 in a rim).

With regard to claim 24, the component is a rigid endplate (2).

With regard to claim 25, the component is polyethylene or other suitable polymeric material (Col 2, lines 48-56).

With regard to claim 31, including two components (such as shown in fig. 1-3 or 10 or 11), one proximate to each of the opposing vertebral endplates; and paths (the channels between

Art Unit: 3738

the 3s) fully capable of having cement injected between each component and its respective vertebral endplate (once installed in the vertebral space but the 3s are not completely anchored. There is a space/channel/groove between the 3s in which a needle could pass and inject cement into the cavity).

Claims 20-25, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buettner-Janz et al. in view of Masini (US 6,273,891). Buettner-Janz et al. discloses a system as discussed above. However, Buettner-Janz et al. remains silent on any instruments for placing cement including an instrument for pressurizing the cement following introduction. Masini discloses another prosthetic system (fig. 3) including an instrument (43) for pressurizing the cement following introduction (Col 5, lines 29-42) for the purpose of filling and sealing the space (37) between prosthetic and bone with cement. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the prosthetic of Buettner-Janz et al to include an injection system as taught by Masini in order to fill and seal space between prosthetic and bone with the cement. Such a modification amounts to mere substitution of one functionally equivalent cement delivery system for another within the art of prosthetics.

With regard to claims 21 and 22, the is a channel/groove is defined by the gap between the 3s

With regard to claim 23, the component includes a peripheral rim to form the cavity (as see in fig. 6, surface 2 conforms around the volume at 8 in a rim, Buettner-Janz et al).

With regard to claim 24, the component is a rigid endplate (2, Buettner-Janz et al).

Art Unit: 3738

With regard to claim 25, the component is polyethylene or other suitable polymeric material (Col 2, lines 48-56, Buettner-Janz et al).

With regard to claim 31, including two components (such as shown in fig. 1-3 or 10 or 11), one proximate to each of the opposing vertebral endplates; and paths (the channels between the 3s) fully capable of having cement injected between each component and its respective vertebral endplate (once installed in the vertebral space but the 3s are not completely anchored. There is a space/channel/groove between the 3s in which a needle could pass and inject cement into the cavity as rejected above, Buettner-Janz et al). Additionally, Buettner-Janz et al as modified includes paths (such as shown in fig 4 of Masini on the implant of Buettner-Janz et al).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

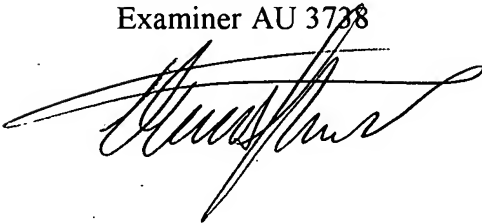
Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner AU 3738

A handwritten signature in black ink, appearing to read 'Thomas J. Sweet', is written over the printed name and title.